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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,566	11/11/2003	Hans-Jurgen Wachter	Heraeus 412-WCG	4253

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EXAMINER	
KESSLER, CHRISTOPHER S	

ART UNIT	PAPER NUMBER
1742	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,566	WACHTER ET AL.	
	Examiner	Art Unit	
	Christopher Kessler	1742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 16-19 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 15-19 (invention II) are drawn to a process of implanting a medical implant, while claims 1-14 (invention I) are drawn to a medical implant or device. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product as claimed can be practiced with another materially different product, such as a stent of a different composition than claimed in Invention I.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-19 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

2. Responsive to the amendment filed 17 July 2007, claims 4-9 and 14 are amended. New claims 15-19 are added, and claims 16-19 are withdrawn as being drawn to a non-elected invention. Claims 1-15 are currently under examination.

Status of Previous Rejections

3. The amendment to claims 8 and 9 and the addition of new claim 15 require new grounds for rejection, stated below.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 5-10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. patent 6,767,360 issued to Alt et al. (hereinafter "Alt").

Regarding claim 1, Alt discloses the invention substantially as claimed. Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the range claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious

to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range.

Regarding claim 2, Alt is applied to the claim as stated above.

Regarding claim 3, Alt is applied to the claim as stated above.

Regarding claim 5, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being intra-cavernous.

Regarding claim 6, Alt discloses wherein the medical device is a stent (see abstract, for example), meeting the limitation of being an intravascular implant

Regarding claim 7, Alt discloses wherein the medical device is a stent (see abstract, for example).

Regarding claim 8, Alt teaches that the alloy is used to make a stent (see SUMMARY OF THE INVENTION, cols. 4-9, or fig. 1, for example). The alloy composition of Alt is cited in the rejections above.

Regarding claim 9, Alt teaches that the alloy is used to make a stent (see SUMMARY OF THE INVENTION, cols. 4-9, or fig. 1, for example). The alloy composition of Alt is cited in the rejections above.

Regarding claim 10, Alt discloses wherein an oxidation process passivates the stent (see col. 8, lines 16-44, for example).

Regarding claim 12, Alt discloses wherein the stent is sintered (see col. 6, lines 31-47, for example).

Regarding claim 13, Alt discloses wherein the stent is coated with a layer of niobium oxide (see col. 8, lines 16-44, for example).

6. Claims 11, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt as applied to claims 1-3 above, and further in view of U.S. Patent 6,387,121 issued to Alt (hereinafter "Alt '121").

Regarding claim 11, Alt does not disclose wherein the surface of the metal alloy is coated by iridium oxide by vapor deposition.

Alt '121 discloses a coated stent for vascular and endoluminal applications. Alt '121 clearly teaches that a layer of iridium oxide is coated onto the stent (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at the time of invention to alter the invention of Alt by coating the stent with iridium oxide, as taught by Alt '121 (cited above), in order to provide a means to deliver drugs to preclude thrombosis, as taught by Alt '121 (see SUMMARY OF THE INVENTION, for example).

Regarding claim 14, Alt does not disclose wherein the surface of the metal alloy is coated with stem cells and or a bioactive substance.

Alt '121 teaches that a stent is coated with iridium oxide to act as a carrier for beneficial drugs (see SUMMARY OF THE INVENTION, for example). It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Alt by coating the stent with a beneficial drug, as taught by Alt '121 (cited above), in order to preclude occlusion from restenosis or thrombosis (see SUMMARY OF THE INVENTION).

Regarding claim 15, Alt '121 teaches that the beneficial drug may include a drug to preclude occlusion from restenosis or thrombosis (see SUMMARY OF THE INVENTION, for example), meeting the limitations of the claim.

7. Claims 1, 2, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,845,259 issued to Pacetti et al. (hereinafter "Pacetti"), in view of Alt.

Regarding claim 1, Pacetti teaches that a guide wire is made from a niobium alloy in order to allow the guide wire to appear in MRI (see SUMMARY OF THE INVENTION, for example). Pacetti does not disclose wherein the alloy is a niobium/zirconium alloy.

Alt discloses a niobium alloy for a medical device comprising preferably less than 1% zirconium, remainder niobium (see col. 4, lines 25-50). The compositional range significantly overlaps the ranges claimed by applicant, thus establishing a prima facie case of obviousness for that range (see MPEP §2144.05). It would have been obvious to one of ordinary skill in the art to have selected the claimed compositional range because Alt teaches the same utility over the entire range. Alt further teaches a balloon angioplasty procedure, and it is well known in the art to install a stent *in vivo* through use of a guide wire during a balloon angioplasty (see col. 1, lines 32-51, for example).

It would have been obvious to one of ordinary skill in the art at time of invention to alter the invention of Pacetti by using the specific niobium alloy disclosed in Alt (cited above), in order to make a guide wire that would not distort the magnetic resonance field, as taught by Alt (see col. 2, lines 30-50).

Regarding claim 2, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 3, Pacetti and Alt are applied to the claim as stated above.

Regarding claim 4, Pacetti and Alt are applied to the claim as stated above.

Response to Arguments

8. Applicant's arguments filed 17 July 2007 have been fully considered but they are not persuasive. Applicants have stated that the invention was made prior to the cited prior art, but there is no documentation to prove these statements. The rejections based on the Alt reference are in effect.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Kessler whose telephone number is (571) 272-6510. The examiner can normally be reached on Mon-Fri, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

csk

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